K121133

i-SENS, Inc.
i·sens 465-6 Wolgye-dong, Nowon-gu, Seoul 139-845, Korea Tel. 82-2-916-6191

JUL 10 2012

510(k) Summary

(As required by 21 CFR 807.92)

Type of 510(k): **Special 510(k)**

Submitted By:
i-SENS, Inc.
465-6, Wolgye-dong, Nowon-gu, Seoul 139-845, Korea
Tel.) +82-2-916-6191
Fax) +82-2-942-2514
www.i-sens.com

Contact Person:
Dr. Hyun Joon Oh
Tel.) +82-33-903-0760
Fax) +82-33-748-6191
e-mail: hjoh@i-sens.com

Prepared Date: April 09, 2012

Device Name:
Trade name: **CareSens N Voice Blood Glucose Monitoring System**
Common Name: Glucose Test System

Regulatory Information:

1) Regulation section:	21 CFR 862.1345 Glucose Test System, 21 CFR 862.1660, Quality control material
2) Classification:	Class II, Class I
3) Product Code:	CGA - glucose oxidase, glucose NBW - system, test, blood glucose, over the counter JJX - Quality control material
4) Panel:	Clinical Chemistry (75)

Intended Use:

The CareSens N Voice Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites such as the forearm, palm, thigh, and calf. Alternative site testing should be used only during steady-state blood glucose conditions. The CareSens N Voice Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro*) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The system is intended to be used by a single person and should not be shared. It is not intended for use on neonates and is not for the diagnosis or screening of diabetes.

The CareSens N Single Blood Glucose Test Strips are for use with the CareSens N Voice Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips and alternative sites.

The CareSens Control Solutions are for use with the CareSens N Voice Meter and CareSens N Single Test Strips to check that the meter and the test strips are working together properly and that the test is performing correctly.

Device Description:

The CareSens N Voice Blood Glucose Monitoring System (BGMS) measures the glucose level in whole blood sample by the meter using a small electrical current generated in the test strips. The system consists of the following: the CareSens N Voice Meter, CareSens N Single Test Strips, CareSens Control Solutions with two different glucose concentrations ("Control A" and "Control B" ranges, sold separately), Lancing Device, Lancets, User's manual, Quick reference guide, and Logbook.

Substantial Equivalence Information:

1) Predicate Device

Device name: **CareSens N Blood Glucose Monitoring System**

510(k) Number: **k083468**

2) Comparison with Predicate Device:

The modified CareSens N Voice BGMS has the following features that are

identical to the predicate device:

- Intended use
- Blood glucose level measuring principle
- Fundamental scientific technology
- Operating ranges

The CareSens N Voice BGMS uses the same test strips and control solutions as the predicate device (CareSens N BGMS, k083468), which are CareSens N Test Strips and CareSens Control Solutions. The only difference is in the name of Test Strips (CareSens N Single Test Strips).

The modifications from the predicate device are as follows:

- Meter shape
- Addition of test strip ejector
- Type of battery
- Addition of voice function (The meter includes the voice function to remind or aid the user as a helpful guidance.)
- Change of memory capacity
- Change of average range
- Change of temperature error message
- Addition of temperature display
- Addition of hypoglycemia indicator

Comparison between the Predicate Device and Candidate Device

Features	Predicate Device	Candidate Device
	CareSens N BGMS (k083468)	CareSens N Voice BGMS
Intended Use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	
Enzyme	Glucose Oxidase	
Measurement principle	Amperometric Method	

Features	Predicate Device	Candidate Device
	CareSens N BGMS (k083468)	CareSens N Voice BGMS
Test Principle	Electro-chemical Reaction	
Sample	Capillary Whole Blood	
Test Time	5 Seconds	
Sample Volume	Minimum 0.5 μL	
Test Range	20 – 600 mg/dL	
Temperature	50 - 104°F (10 - 40°C)	
Operating Humidity	10 – 90%	
Hematocrit Range	20 – 60%	
Battery Life	1,000 tests	
Test Strip Ejector	N/A	Available
Battery	Two(2) 3.0V Lithium batteries (CR2032)	Two(2) 1.5 Alkaline batteries (LR03, AAA)
Voice Function	N/A	Available
Memory Capacity	250 measurement results	500 measurement results
Averaging	14 days	1, 7, 14, 30 and 90 days (Pre-meal, Post-meal, and Total)
Temperature Error Message	Display Er.3 for the temperature below 50°F or above 104°F	Display Lo°F for below 50°F Display Hi°F for above 104°F
Temperature Display	N/A	Displayed
Hypoglycemia Indicator	N/A	Available

Type of Test: Quantitative, Amperometric method, Glucose oxidase *(Aspergillus sp.)*

Test Principle: The enzyme with other reagent on the test strip produces a small electrical current using glucose as a substrate in the blood sample. The current generated is proportional to the amount of glucose present in the sample. The Meter converts the electrical current to a concentration of glucose using the standard curve uploaded in the meter.

Technological The CareSens N Voice BGMS has the same fundamental scientific technology

Characteristics: as the predicate CareSens N BGMS (k083468).

Assessment of Performance Characteristics: When compared with the predicate device (CareSens N BGMS, k083468), the basic features of the CareSens N Voice BGMS (including the intended use, glucose level measuring principle, and fundamental scientific technology) are the same. The CareSens N Voice BGMS uses the same test strips (just a different name) and Control Solutions being used in the CareSens N BGMS. Thus, the candidate device is substantially equivalent to the predicate device (k083464) in aspect of performance, safety, and effectiveness. However, in order to confirm the modifications have not introduced any adverse effect, validation testing including the meter function test and system accuracy test were conducted. Also, to evaluate the usability the CareSens N Voice meter, the human factor study was conducted. The test results confirmed that the modified features operated properly when compare to the predicate device (CareSens N BGMS, k083468). CareSens N Voice BGMS demonstrated satisfactory performance and is suitable for its intended use.

Summary of Pre-cleaning and Disinfection: Disinfection study of the CareSens N Voice meter and its lancing device was conducted by an outside commercial testing service. The study used the CLOROX GERMICIDAL Wipes (EPA Reg. No: 67619-12) as a disinfectant and live virus inoculated on the materials of the meter and lancing device. The result showed that the disinfectant completely inactivated live virus indicating the effectiveness of disinfectant in preventing the spread of blood-borne pathogens, particularly hepatitis B virus (HBV).

We have also demonstrated that 260 pre-cleaning and 260 disinfection cycles (designed to simulated 5 years of use by lay users) has no effect on the performance or the external materials of the meter and lancing device. This demonstrated the robustness of the meter and lancing device after following the recommended pre-cleaning and disinfection protocol.

Conclusion: **Based on the information provided in this submission, the CareSens N Voice BGMS is substantially equivalent to the predicate device (CareSens N BGMS, k083468). The CareSens N Voice BGMS has met the safety, and effectiveness of the device for its intended use.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

i-SENS, Inc.
c/o Hyun Joon Oh
Division Manager, Quality Assurance
465-6 Wolgye-Dong, Nowon-Gu
Seoul, Republic of Korea 139-845

JUL 10 2012

Re: k121133
Trade Name: CareSens N Voice Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: June 12, 2012
Received: June 14, 2012

Dear Hyun Joon Oh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: CareSens N Voice Blood Glucose Monitoring System

Indications for Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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